STENT FOR BIFURCATED VESSELS

Cross-Reference to Related Applications

This application is a continuation-in-part of co-pending patent application Serial No. 10/232,774, filed August 31, 2002 ("the '774 application"), which is a CIP of US 6,478,815, issued November 12, 2002 ("the '815 patent.

Background of the Invention

The present invention relates generally to stents that are implantable or deployable in a vessel or duct within the body of a patient to maintain the lumen of the duct or vessel open, and more particularly to improvements in stent structures.

When inserted and deployed in a vessel, duct or tract of the body, for example a coronary artery after dilatation of the artery by balloon angioplasty, a stent acts as a prosthesis to maintain the vessel, duct or tract (generally referred to as a vessel for convenience herein) open. The stent has the form of an open-ended tubular element with openings through its sidewall to enable its expansion from a first outside diameter which is sufficiently small to allow it to be navigated through the vessel to a target site where it is to be deployed, to a deployed second outside diameter sufficiently large to engage the inner lining of the vessel for retention at the target site.

An occluded coronary artery, for example, is typically attributable to a buildup of fatty deposits or plaque on the inner lining of the vessel. A balloon angioplasty procedure is the treatment of choice to compress the deposits against the inner lining of the vessel to open the lumen. Alternatively, removal of plaque may be achieved by laser angioplasty, or by rotationally cutting the material into finely divided particles which are dispersed in the blood stream. For a large segment of patients undergoing the procedure, traditional angioplasty has resulted in new blockage of the treated vessel only a relatively short time thereafter, attributable to trauma to the blood vessel wall from the original procedure. The mechanism responsible for this restenosis or re-occlusion of the vessel lumen is intimal hyperplasia, a rapid proliferation of smooth muscle cells in the affected region of the wall.

To maintain the vessel open, it has become customary to install one or more stents

at the trauma site at the time of or shortly after the angioplasty procedure is performed. The stenting procedure is recommended for virtually all patients, since those who are predisposed to restenosis are not readily identifiable at the outset. Typically, deployment of the stent is performed by radial expansion under outwardly directed radial pressure exerted, for example, by inflating the balloon of a catheter on which the stent is mounted for implanting in the patient. The expansion is such that the stent engages the inner lining or inwardly facing surface of the vessel wall. The structural characteristics of the stent give it sufficient resilience to allow some contraction from its expanded diameter after the balloon is deflated and the catheter removed from the body, but also adequate stiffness to largely resist the natural recoil of the vessel wall.

Unfortunately, the very presence of the stent in the vessel tends to promote thrombus formation as blood flows through the vessel, which results in an acute blockage. At the outward facing surface of the stent in contact or engagement with the inner lining of the vessel, tissue irritation can exacerbate restenosis attributable to hyperplasia. With current techniques, thrombosis, clotting, and restenosis attributable to installation of the device are reduced or even eliminated by use of drug-eluting stents, and to a somewhat lesser extent, by appropriate choice of the surface characteristics of the stent.

Selection of the material or materials of which the stent is composed is also affected by a patient's allergic reaction. A statistically significant percentage of the patient population who are candidates for stents suffer may severe allergic reaction to common stent materials, including chromium, nickel, and even medical grade 316L stainless steel, which contains about 16% nickel. Implanting a stent composed of these materials in such patients is contra-indicated.

Another consideration in material selection is the need for stent fluoroscopic visibility during the implant procedure, to allow the implanting physician to avoid binding while the stent is navigated on its catheter through the vessel, and to deploy the stent when the desired target site is reached, as well as to permit it to be viewed in periodic examinations of the patient. Thickness of the stent wall is governed not only to enable the stent to withstand vessel wall recoil following deployment, but to assure adequate visibility with fluoroscopy. Nevertheless, the composition and thickness of the stent wall must also

take into account sufficient flexibility to allow the stent to be maneuvered through narrow vessels without binding, and to be deployed under balloon pressurization that will not unduly risk the possibility of rupture.

It follows that a suitable stent for successful interventional placement should possess features of good radiopacity and freedom from distortion during magnetic resonance imaging (MRI), flexibility with suitable elasticity to be plastically deformable, resistance to vessel recoil, sufficient thinness to minimize obstruction to flow of blood (or other fluid or material in vessels other than the cardiovascular system), biocompatibility to avoid vessel re-occlusion, and avoidance of allergic reaction,. As noted above, stent structural design and material selection play a critical role in influencing these features.

Aside from vascular usage, other ducts or tracts of the human body in which a stent may be installed to maintain an open lumen include the tracheo-bronchial system, the biliary hepatic system, the esophageal bowel system, and the urinary tract. Many of the same requirements are found in these other endoluminal usages of stents.

It is quite apparent that technological innovation has yielded considerable progress in the field of interventional cardiology in recent years, such as the successful solution to one of the major problems of restenosis with the advent of drug-eluting stents. Recent clinical trials and usage following regulatory approvals have identified at least two or three different drugs that, when present in a coating on the implanted stent, are locally released from the coating and display a marked capability to inhibit restenosis. Still, bare metal stents remain in use and are implanted and continue to be implanted in large numbers of patients, with resulting restenosis and need for re-intervention that varies between 15% to 40% of patients, depending on vessel size, length (in size) of the stenosis, presence or absence of diabetes, and number and location of stents deployed in the patient. Recent clinical trials have demonstrated that less than 10% of patients receiving implants of drug-eluting stents suffered restenosis during the reporting period, even in patients with small vessels, diabetes, or long (large) stenoses.

A prerequisite of such improved patient response, however, is a need to maintain close contact of the surface of the implanted stent with the vessel wall. The delivery of the drug(s) from the stent coating is a local rather than systemic phenomenon, in which the

stent coating releases a highly lipophilic (hydrophobic) drug that diffuses into the vessel wall in the locale, or immediate vicinity, of the stent implant. It is therefore mandatory that a multitude of small cells, not further away from each other than about 0.5 to 1.0 mm, provide this coverage of the vessel area. If a single stent is implanted, the coverage of the vessel wall and its impregnation by the drug is sufficient, as common trials have shown.

Unfortunately, however, much of the vascular stenosis found in patients involves not merely one vessel, but several sites. Classically, one of the sites for development of restenosis or of an arteriosclerosis is the bifurcation, shown schematically in **FIG. 1A**, where a vessel branches off and divides into either two vessels or a main vessel **10** and a side branch **11**. Arteriosclerotic masses or stenoses **8** are present in both vessel **10** and side branch **11** at the bifurcation. Side branches in the coronary arteries very rarely undergo a 90-degree angulation at take off, but rather, much closer to a 45-degree branching angulation from the main vessel, as shown, by way of example, as angle θ in **FIG. 1A**.

This Figure illustrates the principle dilemma encountered for side branch stenting. The distribution of arteriosclerotic masses **8** in side branch **11** are shown as they normally develop. A mass **8** is present in the main vessel **10**, but other masses **8** are present as well, include the branching off of side branch at **11** at its origin and its proximal and distal sites. To increase the diameter of the main vessel, a balloon catheter is inserted and/or a stent is implanted, to squeeze these masses into he wall of the vessel. The vessel is over-expanded at the site where the stent is implanted, and this provides excellent mechanical scaffolding, which resists reduction in diameter of the vessel from naturally-occurring vessel recoil. But correction of the condition in the side branch is more complex.

FIGS. 1B-1G are schematic diagrams useful in illustrating some of the different techniques attempted in the past to treat stenoses at the branching of a vessel into two vessels or into a main vessel and side branch.

FIGS. 1B and **1C** represent the first two steps common to a sequence of steps that ends with a step illustrated in respective ones of the remaining four parts of **FIG. 1**.

In **FIG. 1B**, a stent **12** is implanted to cover the lesion (stenosis or arteriosclerotic mass, e.g., already subjected to an angioplasty procedure) in the main vessel **10** only, such that the stent also covers the opening of the side branch **11** by a so-called bridging at **14**.

In **FIG. 1C**, a tiny guide wire **15** is advanced through an opening between the struts of the stent **12** in the main vessel **10**, so that the guide wire penetrates into the side branch **11**, and a balloon dilatation is performed by running a balloon catheter over the guide wire into the side branch **11** followed by an angioplasty procedure at target site **16**.

In **FIG. 1D**, a stent **17** mounted on a balloon catheter (not shown), which could be the same balloon catheter used for the angioplasty procedure in **FIG. 1C**, is guided (over the guide wire **15**, not shown in **FIG. 1D** to reduce unnecessary clutter) between struts of stent **12** in the main vessel **10** into side branch **11** and deployed in the side branch, in the form of a T-like implant.

In **FIG. 1E**, an alternative arrangement to that of **FIG. 1D** is illustrated, to implant stent **12** in the main vessel **10** and stent **17** in the side branch **11** such that each stent starts (i.e., has its proximal end) at the place **19** where the bifurcation into the two vessels begins.

In another alternative arrangement, shown in **FIG. 1F**, stent **12** is implanted in the main vessel **10** as in **FIG. 1C**, and stent **17** is implanted through stent **12** in such a way that each stent covers the main vessel **10** in its respective proximal part, with stent **12** overlying stent **17**. The mesh of stent **12** through which stent **17** is installed is opened by inflating the deployment balloon (not shown) through the opening from the main vessel **10** to the side branch **11,** so as to enable blood to flow from the main vessel into and through the side branch.

A similar alternative, shown in **FIG. 1G**, involves a crush technique. Here, stent **12** implanted in the main vessel **10** is completely squeezed to the side by stent **17** implanted into the side branch **11**, but an adequate opening exists in the main vessel at the point of the crushed stent **12** to allow blood to flow through that path as well as through the side branch.

None of these techniques has been shown to have long-term merit, whether with stainless steel (bare metal) stents or with drug coated (drug-eluting) stents. The side branch **11** usually has a diameter about 25-75% of the diameter of the main vessel **10**.

The long-term results of treating bifurcated lesions including a side branch have not been satisfactory. Either an uncovered area is left at the proximal triangle **20** of the side branch **11** (e.g., **FIG. 1D**, and also **FIGS. 1C, 1E**, regarding a similar problem), the size of

which depends on the angulation of the side branch bifurcation, which leaves lesions **8** ready to proliferate again; or too much metal is present in the vessel. In the former case, implanting a stent at the distal origin of the side branch, as shown in **FIG. 1D**, is inadequate to fully cover the inner wall of the side branch in that vicinity because of its geometry. And in the latter case, such as where two stents are implanted so as to overlap each other for full coverage, as in **FIGS. 1F** and **1G**, the resulting large amount of metal in the vessel has yielded very poor results clinically. Even drug coated stents have their limitation in application involving bifurcated lesions.

This inadequacy has two consequences. First, the masses that are squeezed by the stent into the side wall of the artery tend to protrude at any unprotected and uncovered site, making the results of stenting unsatisfactory, not only on an acute basis but also long term. Initial results with drug coated stents also show that restenosis actually develops exactly at this uncovered area. This is attributable to the fact that the restenosis-hindering drug is delivered (eluted) from the stent coating and its distribution into the vessel wall is confined to the immediate vicinity of the stent struts. Accordingly, the uncovered triangle **20** lacks receipt of adequate medication to inhibit proliferation of smooth muscle cells, and restenosis occurs at this location.

Another problem encountered in the past has been that stents are made of stainless steel, which has a rather low radiopacity. Therefore, the stainless steel stent wall diameter must be in a range from 90 to 140 micrometers, which, although this is sufficiently thin and flexible to be advanced through a small artery, in principle, a stent strut thickness of 80 or of even 50 μm would better serve the purpose with greater flexibility and adequate mechanical strength to withstand vessel recoil. But stainless steel stents of such thinness are barely visible, if at all, under fluoroscopy.

Recent developments in stent composition and materials have led to stents that provide a better image than experienced with the bare stainless steel variety in the fluoroscopic catheterization laboratory setting, as well as reduced wall thickness and concomitant greater flexibility, without sacrificing mechanical strength in the radial direction. These advances are achieved, for example, by either a stainless steel stent with a thin layer of appropriate material of greater radiopacity, such as gold, tantalum, or

platinum, which allows the stainless steel base material wall to be made considerably thinner without sacrificing fluoroscopic visibility, as disclosed in patent US 6,099,561 to the applicant herein. Alternatively, use of materials of higher density, such as niobium with a small amount of zirconium as disclosed in the '815 patent, or of multiple sandwich layers of materials having greater radiopacity, which allows the stent to be fabricated with smaller diameter and thinner wall dimension. Other materials that serve this purpose include new alloys of steel and platinum or of cobalt alloyed with chrome, nickel, and molybdenum, or noble metal coatings such as disclosed in US 6,099,561, issued August 8, 2000, also to the applicant herein,. The increased visibility of the stent with these new compositions and techniques applies not only to the stent as a whole, but even to its individual struts.

It is therefore a principal aim of the present invention to describe a system that overcomes the current limitations of side branch stenting.

Summary of the Invention

A presently preferred embodiment of the invention resides in a cooperative stent adapted to be implanted in a patient's body into an acutely angled side branch at a junction of bifurcation from a main vessel, duct or tract. The cooperative stent has an acutely angled end adapted to reside against a portion of a separate main stent implanted in the main vessel, duct or tract bridging the bifurcation junction, such that the cooperative stent when implanted fully covers the inner wall surface of the side branch at the bifurcation junction, with negligible gaps. The stent may be termed "cooperative" in the sense that it cooperates with the main stent to fully cover the lesion present in the main vessel, duct or tract and the side branch at the bifurcation thereof.

The acute angle of the acutely angled end is approximately 45°. And the end of the cooperative stent opposite the acutely angled end is at a different angle from the acute angle, preferably a right angle, relative to the longitudinal axis of the stent. Thus, the acutely angled end of the stent has a short side and a long side connected via an imaginary plane that cuts through the wall of the stent at that end. At least one of the short side and the long side may have an identifying radiopaque parameter or enhanced visibility

characteristic to enable viewing and properly orienting the cooperative stent during implant thereof in the side branch. Indeed, the entire stent may be fabricated from material having enhanced radiopacity without sacrificing thinness, such as observed in the aforementioned '774 application

Preferably also, the outer surface of the cooperative stent has a coating that includes a drug selected to inhibit restenosis, for elution of the drug from the stent when it is implanted in the side branch. Additionally, the acutely angled end of the cooperative stent is adapted to reside against the main stent at an opening along the portion thereof that bridges the bifurcation, to allow a portion of fluid carried by the main vessel, duct or tract, such as blood in the case of coronary artery, to flow relatively unobstructed through the bifurcation junction into the side branch.

In essence, the preferred embodiment may be characterized as a stent having a single straight tubular wall patterned with a plurality of interconnected struts having voids therebetween, and a pair of openings at opposite ends of the wall, the ends being skewed relative to one another. One of the skewed ends has either a fluoroscopically visible marker for properly orienting the stent during implantation, or enhanced visibility as a whole.

Alternatively, the stent may be characterized as a single tube with a multiplicity of through-holes in its side, and one of its two open ends skewed relative to its side, whereby to enable the stent to be implanted in mating relation to the geometry of a side branch similarly skewed relative to a main blood vessel at a bifurcation thereof. And the one skewed end is fluoroscopically identifiable to enable proper orientation of the stent during implantation in the side branch.

According to another aspect of the invention, the stent adapted to be implanted in a side branch at the skewed bifurcation from a main blood vessel in a patient's body, is mounted on a stent delivery system, preferably a balloon catheter, for navigation through the main vessel and deployment of the stent in the side branch at the bifurcation. One of the stent's open ends is angled to match the skew of the bifurcation of the side branch; and the stent is mounted on the balloon catheter with its matching angled end positioned proximally on the catheter. At least one of the stent or the balloon catheter has a fluoroscopically visible characteristic or marker at the matching angled end of the mounted

stent for properly orienting the stent during its deployment in the side branch. Alternatively, at least one of the stent and the balloon catheter has fluoroscopically identifiable markers at the shorter and longer sides of the matching angled end of the mounted stent to facilitate rotation of the catheter and proper orientation of the stent for deployment in the side branch. A radiopaque characteristic or marker may also be present at the opposite end (the right-angled end) of the stent, either on the stent itself or on the balloon or catheter immediately adjacent that end of the stent.

Yet another aspect of the invention resides in a method of implanting a stent in a side branch at a skewed bifurcation from a main blood vessel in a patient's body. A first step of the method involves navigating a balloon catheter through the main vessel to the bifurcation. A stent is mounted on the catheter with the stent's matching angled end to the skew of the side branch bifurcation positioned proximally on the catheter. The navigation of the catheter continues until the stent is positioned in the side branch at the bifurcation. Next, the catheter is rotated to an extent necessary to orient the stent's matching angled end for substantially complete coverage of the inner wall of the side branch at the bifurcation. Finally, the stent is deployed against the inner wall of the side branch to effect that coverage by inflating the balloon of the catheter, and the balloon is then deflated and the catheter is withdrawn, leaving the stent in place.

Still another aspect of the invention pertains to the manufacture of a stent specifically adapted for implantation in a side branch at the origin of the bifurcation thereof from a main vessel, wherein the manufacture or fabrication of the side branch stent is preferably carried out by starting with a single metal tube of appropriate length, diameter and wall thickness and having at least one of its open ends angled at 90° (or approximately so) relative to the longitudinal axis of the tube. The sidewall of the tube is then patterned with a multiplicity of through holes either before or after the other open end of the tube is cut at an acute angle chosen to match the skew angle of the side branch bifurcation from the main vessel, nominally 45°. The through-hole pattern is produced such that the tube diameter may be expanded from its starting dimension, which is sufficiently small to allow the tube to be inserted (by means of a stent delivery system) into a vessel, duct or tract of the patient's body designated to undergo a stenting procedure, to a diameter of adequate

dimension when deployed to hold the side branch lumen open for fluid (e.g., blood) flow therethrough. The final stent may be coated with a know drug or carrier of a drug suitable for elution from the stent when in place in the side branch to inhibit stenosis or restenosis of the side branch inner wall. The acute skew-matching angle of what is to be the proximal end of the stent when implanted, is preferable formed at an angle of 45°, since that angle serves to match the large majority of skews of bifurcations from a main vessel, and will allow an inventory of the side branch stents to be maintained at the place where stenting procedures are to be performed, without a need for custom fabrication or maintaining inventories of such stents with various acute angled ends. However, different angulations other than 45° are feasible and beneficial as well.

Therefore, it is a principal aim of the present invention to provide a stent that is designed to give full coverage of the inner wall of a side branch at the skewed bifurcation of the side branch from a main vessel, with no or only negligible gap relative to a stent bridging the bifurcation in the main vessel.

Another aim is to provide a stent with one its open ends angled to match the skew of the bifurcation of a side branch in which the stent is to be implanted from a main vessel.

Still another aim of the invention is to provide a stent mounted on a balloon catheter with an end of the stent, angled to match the bifurcation skew of a side branch at which the stent is to be deployed, positioned proximally on the catheter.

Yet another aim is to provide a method of implanting a stent in a skewed bifurcation from a main vessel for substantially full coverage of the side branch wall at the bifurcation against which the stent is deployed, regardless of the angle of the skew.

It is noteworthy that the technical problems associated with side branch stenting have been studied extensively, and many proposed solutions have been advanced in the prior art, but none of these proposals rises to the level of the solution advanced by applicant herein. Examples of the prior art proposals are set forth below.

US patent application 2003/0187494 of Loaldi, titled "Endoluminal Device for Delivering and Deploying an Endoluminal Expandable Prosthesis," published October 2, 2003, describes a device that has enhanced delivery capacity. Figure 55 of this patent application shows two stents implanted next to each other to fit the shape of a bifurcation

and to cover two branches, but not the main vessel. The application discusses device operation with two wires, and the practicality of deploying into two different sites.

US patent application 2003/0181972 of Re, published September 25, 2003, describes an MRI and x-ray compatible stent material of tungsten-rhenium that provides increased stent visibility, but no side branch stenting by special means.

US patent application 2003/0097169 of Brucker et al., titled "Bifurcated Stent and Delivery System," published May 22, 2003, discloses how bifurcation into one main stent integrates the side branch stent.

US patent application US 2003/0009209 of Hojeibane, titled "Bifurcated Axially Flexible Stent," published January 9, 2003, describes in Figure 11 a stent with asymmetric ends having two different angulations.

US application US2002/0095208 of Gregorich et al., titled "Stent," published July 18, 2002, describes a stent that allow side branch access, but has angular ends on both its sides.

Various bifurcated stent designs are described, for example, in patents US 6,086,611; US 6,129,738; US 6,602,225; and US 6,540,779B2. In US 6,514,281 a single Y member is used to cover a bifurcation by means of a single stent that extends into both vessels. US 6,080,191 to Summers also discloses a two-legged stent, as do US 4,994,071; US 5,749,825; and US 5,755,771.

US 6,540,777 evaluates and suggests a locker mechanism for stents.

Generally, these suggestions configure the acute technical implantation outcome, but fail to consider the long-term consequences of stenting a side branch for local smooth muscle cell growth, the shifting of plaque material, or the requirements of drug-coated stents. Moreover, none of the prior art designs of which the applicant herein is aware, with the possible exception of the radiopaque tungsten material of US patent application 2003/0181972, discuss a need or desire for increased visibility. Additionally, use of a marker to identify more closely the location and position of an endovascular graft supported by a stent, as described in US 6,361,557 is only to address a concern for graft placement.

Brief Description of the Drawing

The above and still further aims, objectives, features, aspects and attendant advantages of the present invention will be better understood from a consideration of the following detailed description of a best mode presently contemplated of practicing the invention, by reference to certain preferred embodiments and methods of fabrication and thereof, taken in conjunction with the accompanying drawings, in which:

FIGS. 1A-1G are schematic diagrams, discussed in terms of prior art proposed solutions in the Background section above, namely:

FIG. 1A illustrates the multiple sites of vascular stenosis or arteriosclerotic masses at or in the vicinity of a bifurcation from a main vessel into a side branch in the patient's body.

FIGS. 1B and **1C** are schematic diagrams of initial steps typically employed in the prior art in a sequence that leads to respective ones of the solutions illustrated in the remaining four parts of **FIG. 1**.

FIG. 1D is a schematic diagram of a proposed prior art solution in which separate stents are implanted in the main vessel and a bifurcated side branch.

FIG. 1E is a schematic diagram of an alternative prior art proposed solution to that of **FIG. 1D** in which V-type stenting is performed, with a stent implanted in the main vessel and a cooperative stent implanted in the side branch, the two abutting each other at the point where the bifurcation commences.

FIG. 1F is a schematic diagram of another alternative prior art solution, in which a stent is implanted in the main vessel, followed by implanting a second stent in the side branch through the main stent.

FIG. 1G is a schematic diagram of yet another prior art alternative solution, in which a crush technique is used to implant the stent into the side branch through the stent in the main vessel by completely squeezing the latter to the side.

FIG. 2A is a schematic diagram of the side view of a side branch stent according to the present invention.

FIG. 2B is a schematic diagram of the side branch stent of **FIG. 2A** implanted in relation to a main stent.

FIG. 3A is a schematic diagram of the side branch stent of **FIG. 2** properly mounted on a balloon catheter.

FIG. 3B is a schematic diagram of identifying markers used in conjunction with the side branch stent of **FIG. 3B** mounted on a balloon catheter, for aiding rotation and proper orientation of the side branch stent during deployment.

Detailed Description of the Best Mode of Practicing the Invention

According to a principal aspect of the invention, a single stent **37** (**FIGS. 2A** and **2B**) is fabricated to exhibit different angulations at its proximal end **39** and distal end **40**, the angulation at its proximal end (relative to the locus of its implantation on a balloon catheter) being arranged to match the angulation of a side branch **31** (in which stent **37** is intended to be implanted) at its bifurcation (junction) **34** from a main vessel **30**. In particular, the stent **37** is adapted to be implanted in the side branch **31** at a skewed bifurcation from main vessel **30** in a patient's body, by means of a stent delivery system (described more fully below) including a balloon catheter on which the stent is mounted for navigation through the main vessel and deployment of the stent in the side branch at the bifurcation. The stent **37** has one of its open ends **39** angled to match the skew of the bifurcation of the side branch, and when the stent is mounted on the balloon catheter so that its matching angled end is positioned proximally thereon.

The angulation is such that the side branch stent **37**, when properly implanted, lies with that angled end **39** positioned directly against a portion **35** of the side of a stent **32** in the main vessel that bridges the bifurcation junction **34**, with only a virtually negligible gap **36**, if any, between the two stents **32** and **37**. The distal end **40** of the side branch stent has a 90-degree angulation relative to its longitudinal axis 41, whereas the proximal end **39** of the side branch (or cooperative) stent **37**, which is intended to reside at the origin (i.e., the bifurcation junction **34**) of the side branch **31** stemming from the main vessel **30**, has an angulation α that deviates from this rectangular configuration. The stent **37** thus has a side of **50** of relatively short length, and a side **51** of relatively longer length.

The applicant herein has determined that the most suitable and appropriate angle α for the proximal end **39** of the side branch stent **37** is a 45-degree angulation, which covers

the majority of the angles of the branching off of a side branch from a main vessel. This angulation determines the extent of coverage of the inner vessel wall of the side branch **31** can be achieved by stent **37** at the origin of the side branch. As shown in **FIG. 2B**, the optimum coverage is full or complete coverage, in which the proximal end **39** of side branch stent **37** abuts directly against the main stent **30** bridging portion **35** of bifurcation **34**. With this optimum coverage the gap **36** is effectively zero. In practice, however, unless the angulation **α** of proximal end **39** exactly matches that of the bifurcation of the side branch **31** from main vessel **30**, some gap **36**, albeit relatively negligible, will exist when the stent **37** is implanted. But even if the proximal end **39** protrudes slightly (not shown) into the main vessel **30** at the bifurcation **34** when stent **37** is implanted, that slightly protruding portion can be squeezed against the side of the inner wall of the main vessel (and the side branch) by inflating the balloon of a balloon catheter (shown and discussed with regard to **FIGS. 3A** and **3B**, below) during deployment.

It is most important, especially with drug-coated (drug-eluting) stents, that as much as practicable, full coverage of the inner wall of side branch **31** be achieved at and adjacent the bifurcation junction **34**. Otherwise, any substantial uncovered portion of the inner wall would have a tendency toward restenosis, attributable to limited drug concentration (which is highly localized to the extent of the stenting) and to a lack of mechanical scaffolding in the uncovered area. While it is possible to fabricate and tailor the angle of the proximal end 39 of the side branch stent **37** to match a particular angulation of the bifurcation in of each side branch **31** -- in practice for example, by creating an inventory of stents having one angled end within the range of angles most likely to be encountered in stenting -- it is preferred for the sake of convenience, that the side branch stent **37** be manufactured, by conventional techniques, with a proximal end angled at **45°** from the longitudinal axis **41** of the sten, according to the angulation of side branches most prevalent in the body, and particularly in the coronary arteries.

The distal end **40** of side branch stent **37** is preferably angled at **90°** relative to the longitudinal axis **41** of the stent, so as to avoid problems of binding and perhaps even penetrating the vessel wall when advancing the stent through the vascular system to the

target site at which the stent is to be deployed. Furthermore, no particular need exists to deviate with the distal end from the angle of the conventional stent end.

As shown in **FIGS. 3A** and **3B**, for purposes of implanting the side branch stent **37**, it is mounted on the balloon **43** adjacent the distal end **44** of a balloon catheter **45**, in the usual manner. In the case of the present invention, however, the optimally angled end **39** of the stent **37** is to be positioned at the proximal end of the balloon **43** of catheter **45**. Of course, this is done to assure that the stent will be properly oriented for implantation in the side branch. During navigation of the catheter **45** through the vascular system and into the main vessel and beyond, the balloon **43** is maintained in an evacuated or deflated state, as opposed to the partially or fully inflated state shown in **FIGS. 3A** and **3B**, for ease of advancement to the target site. The catheter **45** has an open lumen to allow it to be navigated in over-the-wire fashion on a guide wire **47** previously inserted into the main vessel **10** and ultimately into the side branch **31** in which the side branch stent **37** is to be deployed. Stent **37** may be deployed before or after main vessel stent **32** is implanted, but if deployed afterward it must either be navigated through the mesh sidewall of the main vessel stent at the bifurcation, or the main vessel stent must have its sidewall opened at the bridging portion **34** of the bifurcation junction, as by an earlier opening with a balloon catheter.

Once the side branch stent **37** is in place at the origin **34** (**FIG. 2B**) of the side branch **31**, it becomes necessary to assure that stent **37** is oriented with the longest length **51** of its sidewall arranged to match the inner wall angle of the most proximal point of branching of the bifurcation. To that end, unless the stent **37** is fortuitously oriented in that way, it must be rotated to achieve that orientation by appropriately rotating the catheter **45**. Once that is done, the side branch stent **37** may be deployed by inflating the balloon **43** of catheter **45** until the stent sidewall is pressed firmly against the inner wall of the side branch **31** at its origin. The pressurizing agent within the balloon **43** may then be evacuated, and the catheter **45** withdrawn from the body, leaving stent **37** implanted in place at the origin of the bifurcation.

This leads to the description of a second feature of the side branch stent and methodology of the present invention, namely visibility. Depending on the rotation, the

longer part **51** of the stent **37** can be placed either in direction of the proximal origin of a side branch as shown in **FIG. 2B**, or toward a distal origin (not shown). To allow a correct placement, the stent is preferably composed of a material that allows identification of the asymmetric ends **39** and **40** defined by different side lengths **50** and **51**, as shown in **FIGS. 2A** and **2B**. Suitable materials or coatings having the radiopacity and other characteristics necessary to enable such identification under fluoroscopy as the stent-mounted catheter is navigated into position in the patient's vascular system are described in the applicant's aforementioned '561 application and '815 patent, for example.

Another means suitable for identification of the two ends of the side branch stent and to facilitate its rotation and proper orientation for implantation involves the use of radiopaque markers at one or both ends of the catheter **45** shaft immediately adjacent the respective ends of balloon **43** (**FIG. 3B**). The marker or markers, for example of gold, platinum, or other noble metal, such as at point **56** on the distal end and/or at point **57** for the shorter side **50** and/or at points **58** for the longer side of the stent **37**, serve to identify a critical point or points of the stent so as to allow the stent to be rotated into proper position for deployment and implantation with optimum coverage of the inner wall of the side branch **31** at the locus of the bifurcation origin. The markers may be placed either inside or outside the stent in its mounting location on the balloon **43** of the stent delivery system.

If an unequal number of markers is used, for example two or three markers used at one end to identify the longer side, and a single marker used on the opposite end to identify the shorter side of the stent, rotation of the shaft and balloon of the stent delivery system can separate the two sets of markers. For example, if the catheter is rotated in the anterior posterior position both markers will overlap if they are at the same latitude or length of a stent and, thus, are not identifiable individually. This presents a warning to the implanting physician that the stent is not properly positioned for deployment at the bifurcation origin. In contrast, maximum separation of the two sets of markers would identify the stent as being rotated into the proper position and orientation for deployment. Preferably, however, the entire stent is composed or marked with radiopaque material. Alternatively, the thickness of the stent wall at each of its ends is greater to render those asymmetric ends more radiopaque, for aiding implantation of the stent in the proper orientation and position.

The final side branch stent to be implanted in the patient may be coated with a known drugs or drugs, or a carrier incorporating a drug or drugs, which are adapted to be eluted from the stent when deployed in the side branch to inhibit stenosis or restenosis of the side branch inner wall, and as well to inhibit clotting (thrombosis) within the lumen of the side branch.

Although a best mode of practicing the invention has been disclosed by reference to a preferred method and embodiment, it will be apparent to those skilled in the art from a consideration of the foregoing description that variations and modifications may be made without departing from the spirit and scope of the invention. Accordingly, it is intended that the invention be limited only by the appended claims and the rules and principles of applicable law.